Filed: January 7, 1997

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

Nos. 94-1520(L)
(CA-93-1072-S)

Eugene Duvall, et al,

Plaintiffs - Appellants,

versus

Bristol-Myers-Squibb Co., etc., et al,

Defendants - Appellees.

O R D E R

The Court amends its opinion filed December 18, 1996, as follows:

On page 2, section 4, line 6 -- "Davis S. Toepfer" is corrected to read "David S. Toepfer."

For the Court - By Direction

/s/ Patricia S. Connor

Clerk

PUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

EUGENE DUVALL; PATRICIA SUE DUVALL,
Plaintiffs-Appellants,

v.

BRISTOL-MYERS-SQUIBB COMPANY, a Delaware Corporation; MEDICAL ENGINEERING CORPORATION, a/k/a Surgitek/Medical Engineering Corporation,
Defendants-Appellees,

No. 94-1520

and

FOOD & DRUG ADMINISTRATION,
Amicus Curiae.

EUGENE DUVALL; PATRICIA SUE DUVALL,
Plaintiffs-Appellants,

v.

BRISTOL-MYERS-SQUIBB COMPANY, a Delaware Corporation; MEDICAL ENGINEERING CORPORATION, a/k/a Surgitek/Medical Engineering Corporation,
Defendants-Appellees.

No. 96-1358

Appeals from the United States District Court for the District of Maryland, at Baltimore.
Frederic N. Smalkin, District Judge.
(CA-93-1072-S)

Argued: October 29, 1996

Decided: December 18, 1996

Before WIDENER and WILKINS, Circuit Judges, and MICHAEL, Senior United States District Judge for the Western District of Virginia, sitting by designation.

Affirmed in part, reversed in part, and remanded by published opinion. Judge Wilkins wrote the opinion, in which Judge Widener and Senior Judge Michael joined.

COUNSEL

ARGUED: David Benjamin Shapiro, Baltimore, Maryland, for Appellants. Peter Rolf Maier, Appellate Staff, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Amicus Curiae. Robert T. Shaffer, III, MURPHY & SHAFFER, Baltimore, Maryland, for Appellees. **ON BRIEF:** Lewis J. Saul, Washington, D.C.; Bruce A. Finzen, Gary L. Wilson, David S. Toepfer, ROBINS, KAPLAN, MILLER & CIRESI, Minneapolis, Minnesota, for Appellants. Frank W. Hunger, Assistant Attorney General, Lynne Ann Battaglia, United States Attorney, Douglas N. Letter, Appellate Staff, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Margaret Jane Porter, Chief Counsel, Beverly Rothstein, FOOD AND DRUG ADMINISTRATION, Rockville, Maryland, for Amicus Curiae. William James Murphy, MURPHY & SHAFFER, Baltimore, Maryland; John F. Brenner, MCCARTER & ENGLISH, Newark, New Jersey, for Appellees.

OPINION

WILKINS, Circuit Judge:

These appeals require us to consider anew the effect of the express preemption provision contained in the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, on Eugene Duvall's state-law causes of action against Bristol-Myers-Squibb Company and its wholly owned subsidiary, Medical Engineering Corporation (collectively, "Bristol-Myers").**1** See 21 U.S.C.A. § 360k(a) (West Supp. 1996). In light of the recent decision of the Supreme Court in Medtronic, Inc. v. Lohr, 116 S. Ct. 2240 (1996), we hold that § 360k(a) does not preempt Duvall's claims. We also conclude, however, that the district court correctly granted summary judgment to Bristol-Myers on Duvall's assertion that statements allegedly made to Duvall by a representative of Bristol-Myers constituted an express warranty. Accordingly, we affirm in part, reverse in part, and remand for further proceedings.

I.

In 1990, Duvall was implanted with a penile prosthesis manufactured and marketed by Bristol-Myers. The prosthesis never functioned to Duvall's satisfaction, and eventually Duvall had it removed. Thereafter, Duvall filed suit against Bristol-Myers in Maryland state court, alleging claims for breach of express warranties; breach of implied warranties of merchantability and fitness for a particular purpose; strict liability for defective design, defective manufacture, and failure to warn; and negligent design, manufacture, marketing, promotion, and sale. Bristol-Myers removed the action to federal court on the basis of diversity of citizenship.

The district court granted summary judgment to Bristol-Myers on the basis that all of Duvall's claims were preempted by § 360k(a). On appeal, we affirmed in part, reversed in part, and remanded. See Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392 (4th Cir. 1995) (Duvall I). We held that the plain language of § 360k(a) mandated

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1 We address Patricia Duvall's claim for loss of consortium separately below.

preemption of the majority of Duvall's state-law claims. See id. at 396-400. But, we reversed the grant of summary judgment on the express warranty claims and remanded for further proceedings, concluding that § 360k(a) preempted an express warranty claim only "to the extent that [the claim] is based on FDA-mandated labeling, packaging, and advertising." Id. at 401. Duvall then filed a petition for a writ of certiorari seeking review by the Supreme Court, which granted the writ, vacated our opinion in Duvall I, and remanded for further consideration in light of its decision in Medtronic. See Duvall v. Bristol-Myers-Squibb Co., 116 S. Ct. 2575 (1996) (mem.). While Duvall's petition for a writ of certiorari was pending before the Supreme Court, the district court granted summary judgment to Bristol-Myers on the express warranty claims, and Duvall appealed that ruling to this court.

We consolidated Duvall's appeal from the decision of the district court with the action on remand from the Supreme Court. Each case presents distinct issues. The remand from the Supreme Court requires us to decide whether, in light of Medtronic, Duvall's state-law claims for breach of implied warranties, design defect, manufacturing defect, and failure to warn are preempted by § 360k(a). Duvall's appeal from the grant of summary judgment to Bristol-Myers on the express warranty claims requires us first to decide whether the district court correctly held that Duvall failed to establish a genuine issue of material fact with respect to his assertion of an express warranty based on statements allegedly made by a Bristol-Myers representative. We must then determine the effect of Medtronic on our prior decision that § 360k(a) preempts express warranty claims that are based on FDA-mandated labeling, packaging, or advertising.

II.

Congress enacted the MDA in the midst of rising concern regarding the safety and effectiveness of the growing number of medical devices being introduced into the marketplace. See Medtronic, 116 S. Ct. at 2246. The MDA "provide[s] for the safety and effectiveness of medical devices" by classifying them according to the amount of risk they present to the public and imposing appropriate controls. Id. at 2245, 2246 (internal quotation marks omitted); see 21 U.S.C.A. § 360c (West Supp. 1996). Class I devices, such as tongue depressors,

do not present an unreasonable risk of illness or injury and are subject only to general controls. 21 U.S.C.A. § 360c(a)(1)(A); 21 C.F.R. § 880.6230 (1996). Class II devices, such as bone-conduction hearing aids, for which "general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device," are subject to special controls. 21 U.S.C.A. § 360c(a)(1)(B); 21 C.F.R. § 874.3300 (1996). Class III devices are those devices: (1) for which there is insufficient information to determine that the controls applicable to Class I and II devices are alone enough to provide reasonable assurance of the safety and effectiveness of the device; and (2)(a) that are to be used for "supporting or sustaining human life" or that are "of substantial importance in preventing impairment of human health" or (2)(b) that "present[ ] a potential unreasonable risk of illness or injury." 21 U.S.C.A. § 360c(a)(1)(C). Class III devices are subject to the most stringent MDA controls. See King v. Collagen Corp., 983 F.2d 1130, 1131 (1st Cir.) (Torruella, J.), cert. denied, 510 U.S. 824 (1993). Penile inflatable implants are classified as Class III medical devices. 21 C.F.R. § 876.3350 (1996).

In order to market a Class III device, a manufacturer generally must obtain premarket approval from the FDA. Premarket approval requires submission of a detailed application, including clinical data, manufacturing processes, and proposed labeling, see 21 U.S.C.A. § 360e(c) (West Supp. 1996), and is intended "to provide reasonable assurance of [the] safety and effectiveness" of the device, 21 U.S.C.A. § 360c(a)(1)(C). In the case of a Class III device for which the FDA does not yet require premarket approval, a manufacturer may market the item after showing that it is "substantially equivalent" to a device marketed before the effective date of the MDA. See 21 U.S.C.A. § 360e(b)(1)(B) (West Supp. 1996); Medtronic, 116 S. Ct. at 2247. To do so, a manufacturer must submit a premarket notification, known as a 510(k) notification, including specified information, at least 90 days before marketing a device; the FDA must then authorize the marketing of the device. 21 U.S.C.A. § 360(k) (West Supp. 1996); 21 C.F.R. §§ 807.81-807.100 (1996).

Bristol-Myers' prosthesis reached the market through the substantial equivalence process. Upon completion of clinical trials of the device under an investigational device exemption (IDE), see 21 U.S.C.A. § 360j(g) (West Supp. 1996), Bristol-Myers submitted a

510(k) notification that included information relating to the design and engineering of the device, clinical studies under the IDE, the similarity of the device to other penile prostheses marketed before passage of the MDA, and proposed packaging, labeling, and use instructions. At the FDA's request, Bristol-Myers supplied additional information on sterilization techniques, testing protocols, design of specific components of the device, package inserts, indicated uses, and fluid requirements. The FDA later authorized Bristol-Myers to market the device on the basis that it was substantially equivalent to similar devices marketed before passage of the MDA. In its letter informing Bristol-Myers of the clearance, the FDA noted that "[a]n FDA finding of substantial equivalence . . . does not mean that FDA approves your device."

A.

Before turning to an analysis of the holding in Medtronic, we first briefly review the applicable principles of preemption. The doctrine of preemption, which is based on the Supremacy Clause of the United States Constitution,**2** provides that a state law is invalid to the extent that it conflicts with federal legislation. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992). Preemption occurs in any of several situations. For example, state law is preempted when Congress expressly so provides, see Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977); when federal regulation of a legislative field is so comprehensive that there is no room for supplementary state regulation, see Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947); or when the state law is in actual conflict with a federal provision, see Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n, 461 U.S. 190, 204 (1983).

Because Congress included an express preemption provision in the MDA, we need consider only the scope of the statutory language. See Cipollone, 505 U.S. at 517. The determination regarding the scope of an express preemption provision "does not occur in a contextual vac-

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2 "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

uum," but rather is guided by the twin presumptions "that Congress does not cavalierly pre-empt state-law causes of action" and "that `[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case." Medtronic, 116 S. Ct. at 2250 (alteration in original) (quoting Retail Clerks Int'l Ass'n, Local 1625 v. Schermerhorn, 375 U.S. 96, 103 (1963)).

B.

Section 360k of the MDA provides in pertinent part:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k(a).**3** In Medtronic, the Supreme Court considered the preemptive scope of § 360k(a) with respect to state-law claims against the manufacturer of a pacemaker, a Class III device marketed pursuant to the substantial equivalence process. A divided court concluded that § 360k(a) did not preempt the plaintiffs' state-law claims for defective design, defective manufacture, failure to warn, and failure to comply with FDA standards.

A majority of the Medtronic Court first determined that a state-law damages action may impose a requirement within the meaning of § 360k(a), reasoning that the decision of the Cipollone Court man-

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3 Pursuant to 21 U.S.C.A. § 360k(b) (West Supp. 1996), states and local governments may apply for an exemption from§ 360k(a) under certain circumstances.

dated such a conclusion. See Medtronic, 116 S. Ct. at 2259-60 (Breyer, J., concurring in part and concurring in judgment); id. at 2262-63 (O'Connor, J., concurring in part and dissenting in part). In Cipollone, the Court concluded that the phrase"requirement or prohibition" in § 5(b) of the Public Health Cigarette Smoking Act of 1969 necessarily included common-law claims:

> The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."

Cipollone, 505 U.S. at 521 (plurality) (alterations in original) (quoting San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959)). The members of that Medtronic majority discerned no basis upon which the language of § 360k(a) could be distinguished from the language at issue in Cipollone and, accordingly, concluded that state-law claims are preempted by § 360k(a) to the extent that, if successful, such claims would impose requirements under state law different from or in addition to requirements applicable to a device under the MDA. See Medtronic, 116 S. Ct. at 2259 (Breyer, J., concurring in part and concurring in judgment); id. at 2262-63 (O'Connor, J., concurring in part and dissenting in part).

Second, a different majority of the Medtronic Court concluded that neither the § 510(k) notification process nor the general manufacturing and labeling requirements gave rise to preemption of the plaintiffs' claims under § 360k(a). See id. at 2253-58. With respect to the plaintiffs' design defect claims, the Court determined that the § 510(k) process imposed no requirements with respect to the design of the device and therefore concluded that those claims were not preempted. Id. at 2254-55. The Court reasoned that FDA approval for marketing a device pursuant to a § 510(k) notification constituted nothing more than a judgment that the device in question was similar to a device marketed before passage of the MDA, thus allowing a

post-MDA Class III device to be marketed on the same terms as a pre-MDA Class III device until such time as all devices of that type were required to undergo a more thorough investigation under the premarket approval process. See id. at 2254. Essentially, the Court concluded, § 510(k) approval is merely a means of preserving the status quo that existed before passage of the MDA, including "the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design." Id. at 2255.

The Court also determined that the plaintiffs' state-law allegations that the manufacturer failed to comply with FDA requirements were not preempted. The Court explained that the existence of a damages remedy "for violations of common-law duties when those duties parallel federal requirements" does not necessarily mean that state law imposes a requirement different from or additional to the requirements imposed by the MDA; "rather, it merely provides another reason for manufacturers to comply with identical existing `requirements' under federal law." Id. In reaching this conclusion, the Court found that the ambiguity of § 360k(a) made it appropriate to defer to the assessment of the FDA that § 360k(a) does not preempt state-law "`requirements that are equal to, or substantially identical to, requirements imposed by or under the act.'" Id. at 2256 (quoting 21 C.F.R. § 808.1(d)(2) (1995)).**4**

Regarding the plaintiffs' claims of negligent manufacturing and failure to warn, the Court deferred to the determination of the FDA that § 360k(a) preempts state requirements only when there exist "`specific counterpart regulations or . . . other specific requirements are applicable to a particular device'" under the MDA. Id. at 2257 (quoting 21 C.F.R. § 808.1(d) (1995)). Thus, general requirements imposed pursuant to the MDA--the labeling and good manufacturing practice (GMP) requirements found in 21 C.F.R. parts 801 and 820 (1996)--do not give rise to preemption of state-law claims.

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4 Thus, had Duvall properly alleged that Bristol-Myers failed to comply with FDA requirements, that claim would not have been preempted. However, we previously ruled that Duvall waived this issue by neglecting to present it to the district court. See Duvall I, 65 F.3d at 400 n.7.

In sum, the rule under Medtronic is that state common-law causes of action may constitute requirements, but such requirements are pre-empted only when they conflict with a specific regulation promulgated by the FDA with respect to the particular device in question or a device-specific requirement imposed by the MDA. Accordingly, state-law claims pertaining to medical devices subject only to the general controls imposed by the § 510(k) notification process, GMPs, or labeling requirements are not preempted.

C.

Applying the above analysis to the claims we previously found pre-empted in Duvall I is a relatively straightforward matter. Here, as in Medtronic, the device in question was marketed pursuant to a § 510(k) notification and thus is subject only to requirements of general applicability. Accordingly, we have little difficulty concluding that, under the reasoning of Medtronic, § 360k(a) does not preempt Duvall's state-law claims related to the design, manufacture, marketing, and sale of the product; his failure-to-warn claim; or his breach-of-implied-warranties claim.**5** Indeed, Bristol-Myers does not dispute that, to the extent its prosthesis has the same status under the MDA as the pacemaker at issue in Medtronic, Duvall's state-law claims are not preempted by § 360k(a).

Bristol-Myers argues, however, that Medtronic does not control the outcome of this litigation because here, unlike in Medtronic, the medical device in question was tested under an IDE prior to the submission of a § 510(k) notification. This distinction is important, Bristol-Myers maintains, because the controls applicable to IDE devices are sufficiently specific to give rise to preemption under § 360k(a). We are not persuaded. Regardless of whether the controls applicable to a

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5 Although the Court did not address a claim for breach of implied warranty in Medtronic, we nevertheless determine that the reasoning of that decision requires a conclusion that state-law claims for breach of implied warranties are not preempted by § 360k(a). The decision of the Court cited with approval an FDA regulation listing, inter alia, the Uniform Commercial Code warranty of fitness as an example of the type of state regulation that is not preempted by § 360k(a). See Medtronic, 116 S. Ct. at 2257 (citing 21 C.F.R. § 808.1(d)(1)).

medical device marketed pursuant to an IDE are "specific" federal requirements that give rise to preemption under the reasoning of Medtronic, it is undisputed that the prosthesis implanted in Duvall was not such a device. Rather, the device purchased by Duvall was marketed pursuant to the § 510(k) notification process. Bristol-Myers has provided no support, and we have found none, for the proposition that the controls applicable to IDE devices remain in effect after the IDE has expired. Accordingly, we reject Bristol-Myers' attempt to distinguish this case from Medtronic.

III.

We now turn to the question of whether the district court erred in granting summary judgment to Bristol-Myers on Duvall's claims for breach of express warranties. We conclude that the district court correctly granted summary judgment on Duvall's express warranty claim based on oral representations allegedly made to Duvall by a Bristol-Myers representative prior to the implantation of the prosthesis. We determine, however, that the district court erred in deciding that § 360k(a) preempted the express warranty claim based on statements contained in a brochure regarding the prosthesis.

Under Maryland law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." Md. Code Ann., Com. Law I § 2-313(1)(a) (1992). Breach of an express warranty occurs "when a product fails to exhibit the properties, characteristics, or qualities specifically attributed to it by its warrantor, and therefore fails to conform to the warrantor's representations." Mercedez-Benz of North America, Inc. v. Garten, 618 A.2d 233, 239 (Md. Ct. Spec. App. 1993) (internal quotation marks omitted). Here, Duvall asserted two express warranty claims, one based on oral representations allegedly made to him prior to the surgery and the other based on product literature distributed by Bristol-Myers:**6**

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6 Bristol-Myers makes much of the fact that, in response to a discovery request, Duvall submitted a brochure printed in August 1990, after he had been implanted with the device. After the close of discovery, Duvall

> Prior to the March 16, 1990 penile implantation, I was given and did read a promotional brochure distributed by Bristol-Myers . . . which promised that the implant would allow me to resume sexual intercourse and was given further assurances about the device and its ability to allow me to resume sexual intercourse when I met with . . . a representative of [Bristol-Myers]. It was on the basis of the representations contained in the brochures and the promises made by [Bristol-Myers' representative] that I decided to have the . . . device implanted.

The district court granted summary judgment to Bristol-Myers on the express warranty claim based on oral representations by Bristol-Myers' agent because, it concluded, Duvall had failed to create a genuine issue of material fact. Specifically, the district court held that the conclusory allegations contained in Duvall's affidavit were insufficient to allow a jury to conclude that the representative had made an affirmation of fact or promise regarding the performance of the prosthesis. We agree. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986) (explaining that summary judgment is appropriate when "the evidence is such that a reasonable jury could [not] return a verdict for the nonmoving party"). Moreover, the assertions contained in Duvall's affidavit are contrary to his sworn deposition testimony. See Barwick v. Celotex Corp., 736 F.2d 946, 960 (4th Cir. 1984) (noting that "[a] genuine issue of material fact is not created where the only issue of fact is to determine which of the two conflicting versions of the plaintiff's testimony is correct").

The district court concluded that Duvall's second express warranty claim was preempted under the reasoning of Duvall I because Bristol-Myers had submitted a similar brochure with the materials supporting

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produced a substantially similar brochure printed in 1989, prior to his surgery. We agree with the district court that Bristol-Myers could not possibly have been harmed by the late submission of the 1989 brochure because it was virtually identical to the 1990 brochure previously submitted by Duvall. Moreover, Bristol-Myers authored and distributed both brochures and thus cannot colorably claim that it was unaware of the existence of the 1989 brochure.

its § 510(k) notification. Thus, the statements contained in the brochure were mandated by the FDA and could not support an express warranty claim. See Duvall I, 65 F.3d at 401. At the time of its decision, the district court did not have the benefit of Medtronic. And, in light of that decision, we conclude that the district court erred in ruling that Duvall's express warranty claim based on the brochure was preempted by § 360k(a).

We begin our analysis of this issue by noting that nothing in Medtronic calls into question our holding in Duvall I that § 360k(a) preempts an express warranty claim to the extent that the claim is based on FDA-mandated labeling, packaging, or advertising. Indeed, the essence of the holding in Medtronic--that § 360k(a) gives rise to preemption when the FDA has imposed specific requirements on a particular device--lends credence to our previous conclusion that when the FDA requires the manufacturer of a device to employ certain words to convey information about its product, § 360k(a) operates to preempt differing or additional state-law requirements. However, the decision of the Court in Medtronic constrains us to reconsider the view we expressed in Duvall I that statements contained in proposed labeling, packaging, and advertising submitted with a § 510(k) notification become "FDA-mandated" statements when the FDA clears the device for marketing. To the contrary, Medtronic explicitly holds that neither the § 510(k) notification process nor the general controls on labeling found in 21 C.F.R. part 801 impose requirements on a device sufficient to result in preemption of additional or different state requirements. See Medtronic, 116 S. Ct. at 2254-55, 2258. In light of Medtronic, we hold that Duvall's express warranty claim based on statements included in the brochure advertising the prosthesis is not preempted.

IV.

As construed by the Supreme Court in Medtronic, § 360k(a) of the MDA preempts state-law causes of action to the extent that, if successful, they would impose requirements different from or additional to requirements specifically applicable to the particular device under the MDA. The state-law claims pressed by Duvall in this action, if successful, surely would impose requirements on Bristol-Myers' prosthesis. They are not preempted, however, because there are no spe-

cific federal requirements applicable to the prosthesis.**7** Accordingly, we remand for further proceedings, with the exception of Duvall's assertion of an express warranty based on oral representations allegedly made to Duvall prior to his surgery; as to this claim, we affirm the decision of the district court granting summary judgment to Bristol-Myers.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED

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7 In view of this holding, we reverse the decision of the district court dismissing Patricia Duvall's claim for loss of consortium and remand it for further proceedings consistent with this opinion.